

R E M A R K S

The Office Action, mailed October 11, 2000, has been carefully considered. Favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

First, Applicants respectfully take issue with the Examiner's objection to the Information Disclosure Statement filed 28 June 2000 because copies of certain publications were purportedly not supplied. Copies of these publications were submitted with an Information Disclosure Statement filed in the prosecution of Applicants' parent application on January 4, 1999. They were considered by and thus known to the Examiner. This was confirmed by a paper transmitted to the PTO in the prosecution of this application on September 27, 2000. Reconsideration and withdrawal of this objection are respectfully solicited. Another Information Disclosure Statement is concurrently being filed with this Amendment.

Next, the rejection of claims 1 to 23 "under 35 U.S.C. 112, second paragraph" is respectfully traversed insofar as it not completely overcome by the preceding amendments. Please note that claims 21 to 23 have not been replaced because they are regarded to be very clear and definite. Moreover, there is no criticism of claims 21 to 23 in the comments presented in Paper No. 3.

Claims 1 to 20 have been rewritten as newly presented claims 24 to 43 in a clear and succinct form, which can be readily understood by anyone of ordinary skill in the art. Claims 24-43 find clear and complete antecedent support in the claims they replace, as indicated parenthetically following each new claim number. The dependency of claim 18 (replaced by claim 41) has been changed to overcome the noted defect of the former claim.

Applicants note that each of the art-based grounds of rejection requires a combination of references. Our case law makes clear that the subtle but powerful attraction of a hindsight-based obviousness analysis cannot take the place of a rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically ... the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to

the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 U.S.P.Q. 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

The rejection of claims 1 to 3, 7 to 11, 15, 16, 21 and 22 "under 35 U.S.C. 103(a) as being unpatentable over US 4,590,062 ('062) in combination with the Derwent abstract of Mosques et al, Antihistamines for the treatment of nasal congestion, Allergy, 1996, 51(31):157(AS)" is respectfully traversed. As identified by

the Examiner, the instant application is drawn to a coated tablet comprising:

- a) Mizolastine as biologically active agent;
- b) A fatty matrix (hydrogenated castor oil, hydrogenated lecithin, long chain fatty acids, and esters of triglycerides and medium-chain fatty acids; and
- c) An organic acid (maleic, tartaric, malic, fumaric, citric, lactic, adipic and succinic acids).

On the other hand '062 is directed to a controlled and continuous release form of a biologically active agent, containing a matrix made from a hydrophobic cellulose derivative, a wax, a fatty acid material and/or a neutral lipid (abstract and column 3, lines 10 to 16). The fatty acid consists of from 12 to 28 carbon atoms, such as stearic acid and palmitic acid, and the neutral lipid is, e.g., stearin, palmitin, castorwax (hydrogenated castor oil). Therefore, the "fatty acid and/or neutral lipid" corresponds to the **fatty matrix** of Applicants' claimed invention and nothing more.

The Examiner maintains that '062 teaches that vitamin C (ascorbic acid), which is an organic acid, and antihistamines are suitable biologically active materials for use in the dosage forms (column 4, line 48, and column 5, line 16). However "ascorbic

acid" and "antihistamines" are biologically active agents only. They are not used together nor has this use been intended to by '062 (column 4, line 38, "the biologically active agent...", column 6, line 20).

It is also clear from the examples, which describe a dosage form, that the ascorbic acid is used as a biologically active agent. '062 does not teach, therefore, the combination of fatty matrix and ascorbic acid and antihistamine agent.

Moreover, the present invention concerns a formulation whose dissolution profile is, as described page 2, lines 13 to 20, of the application:

- About 30 to 70% of mizolastine dissolved in 1 hour,
- 100% of mizolastine dissolved in 3 to 5 hours, and
- pH-independent profile.

The dissolution profile of Example 1 of '062 has no relationship to that of the present invention; only 22% of the biologically active agent is released in 1 hour and 56% in 5 hours.

Furthermore, contrary to the Examiner's statement, '062 does not teach "a coated tablet". The coated tablet concerns a dosage form from the prior art.

The Mösges reference was overcome in the prosecution of the parent application by submitting a certified English translation of Applicants' priority document on October 14, 1999.

A copy of that translation is also submitted herewith. The entire ground of rejection is thus completely overcome by antedating the secondary reference.

The rejection of claims 4 to 6, 12 to 14, 17 to 20 and 23 "under 35 U.S.C. 103(a) as being unpatentable over the combination of US 4,590,062 ('062) and Mosques et al....and further in view of US 5,102,666 ('666)" is also respectfully traversed in the same manner and for the same reasons as set forth in the preceding remarks. The added reference does not in any way overcome the previously noted deficiencies of the other two references.

Although '666 concerns a controlled release matrix, the matrix is a hydrogel matrix (column 4, lines 27 to 38) which has nothing to do with a fatty matrix as provided by Applicants' claimed invention. Moreover, the prior art hydrogel matrix is intended to give a release over a very extended period up to several months (column 5, lines 40 to 45).

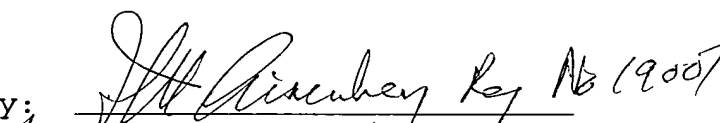
Even though the dosage form may contain antihistamines (column 7, line 7) and organic acid (column 8, lines 10 and 11), there is no combination of a fatty matrix with an organic acid. The organic acid in '666 is used as flavor and does not play the same role.

The provisional rejection of claims 1 to 23 "under the judicially created doctrine of obviousness-type double patenting"

has been noted. Applicants intend to file an appropriate Terminal Disclaimer to overcome that provisional ground of rejection once all other issues are resolved. In view of the foregoing, Applicants believe that the instant response should otherwise place this application in condition for allowance, and confirmation thereof is presently requested.

Respectfully submitted,

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Petition for Extension of Time